§ 20.26 Indexes of certain records.

(a) Indexes shall be maintained, and revised at least quarterly, for the following Food and Drug Administration records:

(1) Final orders published in the FEDERAL REGISTER with respect to every denial or withdrawal of approval of a new drug application or a new animal drug application for which a public hearing has been requested.

(2) Statements of policy and interpretation adopted by the agency and still in force and not published in the FEDERAL REGISTER.

(3) Administrative staff manuals and instructions to staff that affect a member of the public.

(4) Records that have been released to any person in response to a Freedom of Information request and that the agency has determined have become, or are likely to become, the subject of subsequent requests for substantially the same records.

(b) Each such index will be made available through the Internet at http://www.fda.gov. A printed copy of each index is available by writing to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, or by visiting the Freedom of Information Public Reading Room in rm. 12A–30 at the same address.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 68 FR 25285, May 12, 2003]

§ 20.27 Submission of records marked as confidential.

Marking records submitted to the Food and Drug Administration as confidential, or with any other similar term, raises no obligation by the Food and Drug Administration to regard such records as confidential, to return them to the person who has submitted them, to withhold them from disclosure to the public, or to advise the person submitting them when a request for their public disclosure is received or when they are in fact disclosed.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.28 Food and Drug Administration determinations of confidentiality.

A determination that data or information submitted to the Food and Drug Administration will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.29 Prohibition on withdrawal of records from Food and Drug Administration files.

No person may withdraw records submitted to the Food and Drug Administration. All Food and Drug Administration records shall be retained by the agency until disposed of pursuant to routine record disposal procedures.

[42 FR 15616, Mar. 22, 1977, as amended at 68 FR 25285, May 12, 2003]

§ 20.30 Food and Drug Administration Freedom of Information Staff.

(a) The Office responsible for agency compliance with the Freedom of Information Act and this part is:

Freedom of Information Staff (HFI–35), Food and Drug Administration, Room 12A–16, 5600 Fishers Lane, Rockville, MD 20857.

(b) All requests for agency records shall be sent in writing to this office.

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981]

§ 20.31 Retention schedule of requests for Food and Drug Administration records.

(a) Unless unusual circumstances dictate otherwise, the Food and Drug Administration shall maintain and dispose of files of requests and reponses furnished thereto within the time limits authorized by GSA General Records Schedule 14, FPMR 101–11–4, January 10, 1977, as follows:

(1) Files created by the receipt of and response to freedom of information requests, except denials and/or appeals, may be destroyed 2 years from date of final response.

(2) Files created by a freedom of information request which was wholly or partially denied may be destroyed 5 years after the denial letter was issued.

(3) Files created by a freedom of information request which was wholly or partially denied and which denial was subsequently appealed to the Department of Health and Human Services may be destroyed 4 years after final determination by FDA or 3 years after final adjudication by courts, whichever is later.

(b) This destruction schedule will automatically be revised whenever the time limits pertaining to these records are revised by the GSA General Records Schedule.

[47 FR 24277, June 4, 1982]

§ 20.32 Disclosure of Food and Drug Administration employee names.

The names of Food and Drug Administration employees will not be deleted from disclosable records except where such deletion is necessary to prevent disclosure of an informant or danger to the life or physical safety of the employee or under other extraordinary circumstances.

§ 20.33 Form or format of response.

(a) The Food and Drug Administration shall make reasonable efforts to provide a record in any requested form or format if the record is readily reproducible by the agency in that form or format.

(b) If the agency determines that a record is not readily reproducible in the requested form or format, the agency may notify the requester of alternative forms and formats that are available. If the requester does not express a preference for an alternative in response to such notification, the agency may provide its response in the form and format of the agency's choice.

[68 FR 25285, May 12, 2003]

§ 20.34 Search for records.

(a) In responding to a request for records, the Food and Drug Administration shall make reasonable efforts to search for records kept in electronic form or format, except when such efforts would significantly interfere with the operation of the agency's automated information systems.

(b) The term ''search'' means to review, manually or by automated means, agency records for the purpose of locating those records that are responsive to the request.

[68 FR 25285, May 12, 2003]

Subpart C—Procedures and Fees

§ 20.40 Filing a request for records.

(a) All requests for Food and Drug Administration records shall be made in writing by mailing or delivering the request to the Freedom of Information Staff (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, or by faxing it to 301–443–1726. All requests must contain the postal address and telephone number of the requester and the name of the person responsible for payment of any fees that may be charged.

(b) A request for Food and Drug Administration records shall reasonably describe the records being sought, in a way that they can be identified and located. A request should include all pertinent details that will help identify the records sought.

(1) If the description is insufficient to locate the records requested, the Food and Drug Administration will so notify the person making the request and indicate the additional information needed to identify the records requested.

(2) Every reasonable effort shall be made by the Food and Drug Administration to assist in the identification and location of the records sought.

(c) Upon receipt of a request for records, the Freedom of Information Staff shall enter it in a public log. The log shall state the date received, the name of the person making the request, the nature of the record requested, the action taken on the request, the date of determination letter sent pursuant to § 20.41(b), and the date(s) any records are subsequently furnished.

(d) A request by an individual, as defined in § 21.3(a) of this chapter, for a record about himself shall be subject to:

(1) The special requirements of part 21 of this chapter (the privacy regulations), and not to the provisions of this subpart, if the record requested is retrieved by the individual's name or